FDA 510(k) Premarket Notification

K201492 Non-Sterile Zirconia Block

CLEARED

Mar 10, 2021
279 days to decision

K201492 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k201492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jun 4, 2020
Decision date	Mar 10, 2021
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bioden Co., Ltd.**
Location	Seoul, KR
Contact	MyeongEun Song
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	**Med.Com**
Contact	Chris Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov